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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

GABRIELA MENDOZA, *individually and on behalf of all others similarly situated*,

Plaintiff,

v.

THE PROCTER & GAMBLE COMPANY,

Defendant.

Civil Case No.: 2:23-cv-01382-DMG-JPR

NOTICE OF MOTION AND MOTION TO CERTIFY FOR INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(B)

The Hon. Dolly M. Gee
Date: March 1, 2024
Time: 9:30 am
Courtroom 8C

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NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE THAT, at 9:30 am on March 1, 2024, or as soon thereafter as the matter may be heard before the Honorable Dolly M. Gee, presiding in the United States District Court for the Central District of California, located at 350 West 1st Street, Los Angeles, CA, 90012, Defendant The Procter & Gamble Co. ("P&G"), will, and hereby does, move this Court, under 28 U.S.C. § 1292(b), for an order certifying the Court's December 20, 2023 Order Granting in Part and Denying in Part Motion to Dismiss (ECF No. 42) for interlocutory review.

This Motion is based on this Notice of Motion, the Memorandum of Points and Authorities submitted herewith, the Declaration of Jeff Cullinane, any Reply Memorandum or other papers submitted in connection with the Motion, the First Amended Complaint (ECF No. 25), Defendant's Motion to Dismiss (ECF No. 29) and the Reply in Support of Defendant's Motion to Dismiss (ECF No. 32), all other pleadings and papers on file in this action, any matter of which this Court may properly take judicial notice, and any information presented at argument.

This Motion is made following the conference of counsel pursuant to L.R. 7-3. On Thursday, January 18, 2024, counsel for P&G contacted counsel for Plaintiff by e-mail, outlined the substance of this motion, and offered to discuss it further with Plaintiff's counsel. Plaintiff's counsel responded on Friday, January 19 that they would not be available for further discussion on the motion until the following Tuesday, January 23, and did not respond to a request made by counsel for P&G immediately following receipt of that email to confer earlier. P&G's counsel therefore arranged a teleconference for January 23, during which Plaintiff's counsel stated at the outset that it should be a short call and expressed their view that certification for interlocutory appeal was not appropriate.

The two sides also expressed different views regarding the interpretation of L.R. 7-3 and when the seven days between the required conference and the filing of the motion begin to run. P&G maintained that the time began to run from its substantive e-mail on January

18, whereas Plaintiff maintains that it began to run from the teleconference on January 23. In light of this disagreement, P&G's counsel asked Plaintiff's counsel to identify any prejudice to Plaintiff from P&G filing its motion on January 25, *i.e.*, seven days after its substantive e-mail. Plaintiff's counsel identified no prejudice, but instead referred to the need for time to research the issues in order to prepare an opposition to the motion. P&G's counsel offered to address this concern by agreeing to an extension of Plaintiff's opposition deadline. Plaintiff's counsel did not accept this offer, and instead informed P&G that if it filed this motion on January 25, Plaintiff would argue that P&G had violated L.R. 7-3.

Plaintiff is incorrect. P&G discharged its meet-and-confer obligation through its substantive e-mail on January 18, *i.e.*, seven days before filing this motion, and that is not altered by Plaintiff's counsel's unavailability for a teleconference until five days after that outreach. *See Colodney v. Cty. of Riverside*, 651 F. App'x 609, 611 (9th Cir. 2016) ("The district court did not abuse its discretion by declining to find a violation of Local Rule 7-3 because the record indicates that seven days before the County of Riverside filed its motion to dismiss, its counsel both mailed and e-mailed Colodney in an attempt to meet and confer."); *see also Arteaga v. FCA US LLC*, 2020 WL 2857488, at *2 n.2 (C.D. Cal. 2020) (Gee, J.) (citing *Colodney* and finding "substantial[] compli[ance]" with L.R. 7-3 based on plaintiff advising defendant of his intent to file the motion, despite the apparent absence of a live discussion). Further, as reflected by the exchange discussed above, Plaintiff's counsel identified no prejudice resulting from P&G filing this motion on January 25. *See Vahanyan v. Unifund Corp.*, 2012 WL 13254107, at *1 (C.D. Cal. 2012) (Gee, J.) (excusing noncompliance with L.R. 7-3 and proceeding to merits of motion where a movant "fail[ed] to identify any prejudice that [non-movant] has suffered from [movant's] non-compliance with Local Rule 7-3"). P&G remains willing to agree to an extension of time for Plaintiff's opposition.

DATED: January 25, 2024 By: */s/ Ashley M. Simonsen*
Ashley M. Simonsen

Attorneys for Defendant, The Procter & Gamble Co.

STATEMENT OF ISSUES TO BE DECIDED

Whether the Court should certify for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) its December 20, 2023 Order Granting in Part and Denying in Part Defendant's Motion to Dismiss (ECF No. 42), given the substantial grounds for difference of opinion on the following controlling questions of law:

1. Whether the Federal Food, Drug, and Cosmetic Act ("FDCA") expressly preempts state-law requirements to make additional disclosures on the label of an over-the-counter medicine or cosmetic, when the Food and Drug Administration ("FDA") has issued a monograph or other comprehensive regulations governing the product that do not impose the labeling requirement sought by the plaintiff.
2. Whether a plaintiff who has never purchased a particular product has Article III standing to sue for alleged false advertising concerning that product.

I. INTRODUCTION

As this Court stated in its order, "[c]ourts have been heavily split, even within this district, in navigating state-law . . . labeling requirements and FDCA preemption." ECF No. 42 at 4. Similarly, "[t]here is no clear binding authority on whether plaintiffs have standing to sue for products they did not purchase." *Id.* at 10. In light of this Court's accurate observations on the unsettled state of the law applicable to this case, this Court should certify its December 20, 2023 Order for interlocutory review under 28 U.S.C. § 1292(b).

The Court's Order satisfies the three requirements of Section 1292(b) for many of the same reasons that other courts in this district have certified similar issues for review. *E.g., Total TV v. Palmer Commc'ns, Inc.*, 69 F.3d 298, 300 (9th Cir. 1995) (reviewing federal preemption question under Section 1292(b)); *John Lenore & Co. v. Olympia Brewing Co.*, 550 F.2d 495, 496–97 (9th Cir. 1977) (reviewing standing question under Section 1292(b)).

First, the Order involves controlling questions of law. The preemption and standing issues are both purely legal questions. Resolution of the preemption inquiry in P&G's favor

would eliminate all claims related to VapoRub and VapoCream, which are the central products in the case, while a favorable standing determination would at least remove claims covering one of those products.

Second, there is "substantial ground for difference of opinion" concerning these questions, and the Court's Order acknowledges as much for both issues. *See* ECF No. 42 at 4, 10.

Courts have employed differing approaches to determine whether the FDCA expressly preempts state-law requirements. One approach holds false advertising claims preempted when they compel a labeling representation that differs in any way from the labeling statements specified in the FDA regulation governing the product. *See, e.g.*, *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1282 (C.D. Cal. 2008). Another approach holds that federal law preempts state-law requirements if the FDA has considered or regulated the general subject matter at issue in plaintiff's claims, even if it has not expressly addressed the specific language raised by the plaintiff. *See, e.g.*, *Goldstein v. Walmart, Inc.*, 637 F. Supp. 3d 95, 111 (S.D.N.Y. 2022). Under either of these approaches, Plaintiff's VapoRub and VapoCream claims would be preempted: FDA regulations do not require a disclaimer that the children's and non-children's versions are the same, even though they *do* regulate the subject-matter of required labeling for these products, including labeling when marketed for children. In contrast, other courts decline to apply the FDCA's express preemption provisions unless an FDA regulation addresses the specific representation required by the claims. *See, e.g.*, *Slaten v. Christian Dior, Inc.*, 2023 WL 3437827, at *2 (N.D. Cal. May 12, 2023). Absent specific FDA guidance on the discrete issue, such courts consider it sufficient to avoid preemption when both federal and state law prohibit representations that are false or misleading. *See, e.g.*, *Jovel v. i-Health, Inc.*, 2013 WL 5437065, at *6 (E.D.N.Y. Sept. 27, 2013). This Court's Order followed the latter approach while diverging from the first and second. The fact that courts have followed different approaches to the same legal issue—or in this Court's words, the fact that courts

are "heavily split" on the scope of FDCA preemption, ECF No. 42 at 4—demonstrates that there is a substantial ground for difference of opinion as to when the FDCA preempts a state-law requirement.

Courts have likewise reached disparate results on the standing question. This Court held that Plaintiff has standing to sue for a product she did not purchase. But other courts have denied standing for such plaintiffs as a matter of law. *See, e.g.*, *Dysthe v. Basic Research LLC*, 2011 WL 5868307, at *4 (C.D. Cal. June 13, 2011).

Third, certification is likely to advance the ultimate termination of the case. "[A] final, dispositive effect on the litigation" is not required. *See Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 688 (9th Cir. 2011). A favorable resolution of these issues would eliminate all claims related to VapoRub and VapoCream—which together account for 92% of the sales at issue, and thus the vast bulk of the alleged damages. *See* Ex. 1, Declaration of Jeff Cullinane ("Cullinane Decl.") ¶ 4. Reversal on preemption and/or standing would therefore dramatically shrink, simplify, and streamline this litigation, greatly increasing the likelihood of an early and efficient settlement, *see S.E.C. v. Mercury Interactive, LLC*, 2011 WL 1335733, at *3 (N.D. Cal. Apr. 7, 2011), and reducing discovery burdens, *see Ritz Camera & Image, LLC v. Sandisk Corp.*, 2011 WL 3957257, at *3 (N.D. Cal. Sept. 7, 2011). *See also Gillespie v. Centerra Servs. Int'l, Inc.*, 2022 WL 18584762, at *3 (C.D. Cal. Oct. 26, 2022) (interlocutory appeal that could resolve some, but not all, claims would materially advance litigation).

II. BACKGROUND

P&G markets the "Vicks Vapo" brand, a line of topical products including VapoRub, VapoCream, and VapoPatch. Am. Compl. ¶ 1. Each product is available in a version labeled for children and a version without age specifications, both of which contain identical ingredient formulations. *Id.* ¶ 2. Of the combined U.S. sales of the products to retailers during the Class Period of May 2019 to December 2023, VapoRub comprised 88.6%, VapoCream comprised 3.4%, and VapoPatch comprised 8.0%. Cullinane Decl. ¶ 4.

On May 11, 2023, Plaintiff filed an Amended Complaint alleging that the simultaneous marketing of children's and non-children's versions of the "Vicks Vapo" products constitutes deceptive advertising. (Dkt. 25). Plaintiff argues that labeling a version of the products for children creates the false impression that they "are specifically formulated for children," Am. Compl. ¶ 4, and that state law requires P&G to include on the products' labels a disclaimer that the children's and non-children's versions are the same, *see id.* ¶ 42.

P&G moved to dismiss Plaintiff's Amended Complaint on several grounds, including federal preemption and lack of standing. (Dkt. 29).

First, P&G argued that the FDCA preempts Plaintiff's claims concerning VapoRub and VapoCream because the "detailed labeling regulations that authorize the[ir] marketing [] do not require different labeling or disclosures for the children's version" and the version that does not identify an age group. Mot. at 8. The FDCA expressly preempts state law requirements that are "different from," "in addition to," or "otherwise not identical" with federal labeling requirements for over-the-counter drugs and cosmetics. 21 U.S.C. §§ 379r(a)(2), 379s(a). VapoRub is an over-the-counter drug regulated by the FDA through two "monographs"—a set of federal regulations prescribing how a category of over-the-counter drugs may be marketed. *See* 21 C.F.R. § 341.74 (monograph governing antitussives); *see also* 48 Fed. Reg. 5852, 5868 (Feb. 8, 1983) (tentative final monograph governing external analgesics); 21 U.S.C. § 355h(b)(8) (deeming the tentative final monograph a final administrative order carrying force of law). VapoCream is a cosmetic for which a comprehensive FDA regulatory scheme governs labeling requirements. *See* 21 U.S.C. § 361 *et seq.*; 21 C.F.R. § 701 *et seq.* P&G explained that the monographs governing VapoRub (1) specify the precise combination of ingredients for use in a children's version, and (2) address specific labeling requirements for certain other children's products, but do *not* require a disclaimer that the children's and non-children's versions of VapoRub are the same. Likewise, the regulations for VapoCream do not require a representation that the

children's and non-children's versions are the same. Thus, the purported state-law requirement to include such a disclaimer is "in addition to" and "otherwise not identical with" the labeling required by applicable FDA regulations, and the FDCA accordingly preempts Plaintiff's state-law claims concerning VapoRub and VapoCream.

Second, P&G argued that "Plaintiff lacks standing to sue over products she has not purchased because a plaintiff 'has not been injured by false advertising on products she did not purchase.'" Mot. at 23–24 (quoting *McCracken v. KSF Acquisition Corp.*, 2022 WL 18932849, at *2 (C.D. Cal. Dec. 15, 2022)). As such, all claims related to VapoCream should be dismissed for lack of standing.

On December 20, 2023, this Court issued an order granting in part and denying in part P&G's motion to dismiss, in which it rejected P&G's preemption and standing arguments. ECF No. 42 at 4.

Acknowledging that "[c]ourts have been heavily split, even within this district, in navigating state-law . . . labeling requirements and FDCA preemption," *id.*, the Court concluded that Plaintiff's claims concerning VapoRub and VapoCream were not preempted, *id.* at 5. The Court's principal basis for this conclusion was that the "state law claims mirror the FDCA's requirements" that branding not be false or misleading. *Id.* at 5. Thus, because Plaintiff alleged that the lack of a disclaimer concerning the children's and non-children's versions made the labeling "false or misleading," and federal law prohibits false and misleading labeling, her claims were not preempted. *Id.* at 4–5. In a footnote, the Court stated that preemption was not appropriate for the further reason that cases such as *Youngblood v. CVS Pharmacy*, 2021 WL 3700256, at *2 (C.D. Cal. Aug. 17, 2021), are distinguishable. The Court noted that "the FDA does not address whether antitussives and external analgesics for children must specifically denote that they are for children." ECF No. 42 at 5 n.4. On this basis, the Court reasoned, "'[t]here is no FDCA requirement on point, so no preemption.'" *Id.* (quoting *Slaten*, 2023 WL 3437827, at *2 (cleaned up)).

The Court also recognized that "[t]here is no clear binding authority on whether plaintiffs have standing to sue for products they did not purchase." *Id.* at 10. But it concluded that Plaintiff had standing to bring false advertising claims concerning VapoCream despite not purchasing that product, because "VapoCream is sufficiently similar to the products Mendoza did purchase." *Id.* at 11.

III. ARGUMENT

Under 28 U.S.C. § 1292(b), a district court may certify an order for interlocutory appeal if it involves (1) "a controlling question of law," (2) as to which there are "substantial ground[s] for difference of opinion," and (3) "an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b); *see also Reese*, 643 F.3d at 688. The Ninth Circuit has applied a "flexible approach" to this standard to avoid "undesirable consequences," such as "unnecessary, protracted litigation and a considerable waste of judicial resources." *Reese*, 643 F.3d at 688 n.5.

In its Order, this Court correctly recognized that courts have taken conflicting approaches to key legal issues in this case: FDCA preemption and Article III standing. Immediate appellate resolution of these difficult questions would substantially streamline this case and could pave the way to an early and efficient resolution. These issues therefore are paradigmatic examples of questions on which interlocutory appeal is appropriate, and this Court should therefore certify its Order under Section 1292(b).

A. The Order Involves Controlling Questions of Law.

The Court's Order involves "controlling question[s] of law" because the preemption issue and the standing issues raise purely legal questions that could materially affect the outcome of the litigation.

"[A]ll that must be shown in order for a question to be 'controlling' is that resolution of the issue on appeal could materially affect the outcome of litigation in the district court." *In re Cement Antitrust Litig.*, 673 F.2d 1020, 1026 (9th Cir. 1981). "[N]either § 1292(b)'s literal text nor controlling precedent requires that the interlocutory appeal have a final,

dispositive effect on the litigation" as a whole. *Reese*, 643 F.3d at 688; *see also Kuehner v. Dickinson & Co.*, 84 F.3d 316, 319 (9th Cir. 1996) (rejecting argument that "no question of law can be controlling unless it determines who will win on the merits"). Certification is proper if even "one question support[s] certification." *Nat'l Ass'n of Afr.-Am. Owned Media v. Charter Commc'ns, Inc.*, 2016 WL 10647193, at *4 (C.D. Cal. Dec. 12, 2016).

Whether federal law preempts a state-law claim is a controlling question of law. *See, e.g.*, *Hope Med. Enters., Inc. v. Fagron Compounding Servs., LLC*, 2021 WL 6618726, at *5 (C.D. Cal. Apr. 20, 2021) ("whether the FDCA preempts [plaintiff's] state law claims is a purely legal question"); *see also Delarosa v. Boiron, Inc.*, 2011 WL 13130856, at *4 (C.D. Cal. Dec. 29, 2011) (same). Resolving preemption issues can significantly narrow the scope of a case and materially affect the outcome of the litigation—in this case, eliminating all claims relating to the VapoRub and VapoCream products, which are the heart of this case and account for all but a sliver of the alleged damages. *See* Cullinane Decl. ¶ 4. Thus, courts in the Ninth Circuit and multiple other courts of appeals have recognized that a preemption issue presents a controlling question of law worthy of resolution through an interlocutory appeal. *See, e.g.*, *Haley v. Medtronic, Inc.*, 1995 WL 688240, at *1 (C.D. Cal. June 9, 1995) (granting Section 1292(b) certification based on FDCA preemption because "the preemption issue clearly involves a controlling issue of law"); *see also Total TV,* 69 F.3d at 300 (granting review of federal preemption question); *Facenda v. N.F.L. Films, Inc.*, 542 F.3d 1007, 1013 (3d Cir. 2008) (same); *Little v. Louisville Gas & Elec. Co.*, 805 F.3d 695, 697 (6th Cir. 2015) (same); *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 687 (3d Cir. 2016) (same); *Moore v. Apple Cent., LLC*, 893 F.3d 573, 574–75 (8th Cir. 2018) (same).

Likewise, whether a plaintiff has standing to sue for alleged deceptive advertising of a product the plaintiff never purchased is "controlling." Article III standing to sue "is a question of law for the court." *In re W. Liquid Asphalt Cases*, 487 F.2d 191, 199 (9th Cir. 1973); *Johnson v. City of Grants Pass*, 72 F.4th 868, 881–82 (9th Cir. 2023) ("Standing and

mootness are questions of law"). Here, the Article III standing question does not involve any disputed facts because Plaintiff does not allege that she purchased the VapoCream product. *See Pirani v. Slack Techs., Inc.*, 2020 WL 7061035, at *1 (N.D. Cal. June 5, 2020) (granting certification based on standing issue because operative facts of complaint are undisputed). Moreover, appellate resolution of the standing issue in P&G's favor would result in the removal of all claims related to the VapoCream product. Standing is therefore a controlling issue in this case. *See Ritz Camera*, 2011 WL 3957257, at *1–2 (granting Section 1292(b) certification on whether plaintiff had standing to assert antitrust claim); *Olympia Brewing*, 550 F.2d at 496–97 (reviewing standing question under 1292(b) interlocutory appeal).

B. Substantial Grounds Exist for Difference of Opinion.

The second criterion of Section 1292(b) is also satisfied because, as this Court already recognized in its Order, there are substantial grounds for difference of opinion on the Court's conclusions as to both FDCA preemption and standing. *See* ECF No. 42 at 4, 10 (recognizing that other courts have resolved these issues differently).

A "substantial ground for difference of opinion exists where reasonable jurists might disagree on an issue's resolution." *Reese*, 643 F.3d at 688. And "[o]ne of the best indications that there are substantial grounds for disagreement on a question of law," although not a necessary one, "is that other courts have, in fact, disagreed." *Brickman v. Facebook, Inc.*, 2017 WL 1508719, at *3 (N.D. Cal. Apr. 27, 2017) (quoting *Heaton v. Soc. Fin., Inc.*, 2016 WL 232433, at *4 (N.D. Cal. Jan. 20, 2016)). That is true as to both issues here.

1. There Is Substantial Ground for Difference of Opinion on Whether the FDCA Expressly Preempts A State-Law Requirement To Add Labeling Not Required By Relevant Federal Regulations.

This Court correctly recognized that "[c]ourts have been heavily split, even within this district, in navigating state-law . . . labelling requirements and FDCA preemption."

ECF No. 42 at 4. Under the FDCA, states may not establish "any requirement" that is "different from or in addition to, or [] otherwise not identical with" federal labeling requirements. 21 U.S.C. § 379r(a)(2), 379s(a). Courts have applied differing approaches to determine when a state's requirements impermissibly deviate from or supplement federal labeling requirements, creating a demonstrated difference of opinion on when the FDCA preempts state-law claims.

First, several federal courts in this District and elsewhere have held that the FDCA preempts false advertising claims whenever the plaintiff's claims would require a defendant to add a labeling representation to its products that the FDA monograph or other regulation governing such products do not require—whether or not the regulation expressly addresses the issue raised by plaintiff. *See Carter*, 582 F. Supp. 2d at 1283 (highlighting that "[t]he touchstone of preemption under § 379r is the *effect* that a finding of liability on a particular claim would have on the Defendants . . . . As long as that claim imposes a 'requirement' that is at variance with FDA regulations, it is preempted."); *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35–36 (2d Cir. 2020) ("The FDCA preempts not only those state laws that are in conflict with it . . ., but also *any* state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and its regulations (i.e., any law that is 'in addition to' the FDCA)."); *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) ("The disclaimers that the plaintiff wants added to the labeling of the defendants' [products] are not identical to the labeling requirements imposed on such products by federal law, and so they are barred."). Some of these courts have specifically held that, to avoid preemption, a plaintiff must plead facts suggesting that the defendant's label affirmatively violates an FDA regulation. *See Faustino v. Alcon Labs., Inc.*, 2015 WL 12839161, at *2 (C.D. Cal. Sept. 22, 2015), *aff'd*, 692 F. App'x 819 (9th Cir. 2017) (finding negligent misrepresentation claim for failure to warn preempted because "Plaintiff has not alleged that Defendant violated any FDA regulations; thus, the only logical conclusion is that Defendant allegedly violated warning or label requirements that differ from or add to the

FDA regulations."); *Carter*, 582 F. Supp. 2d at 1282 ("Plaintiffs do not allege that Defendants fail to comply with FDA regulations as they currently exist, so none of their claims are parallel enforcement claims.").

The court's reasoning in *Harris v. Topco Assocs., LLC*, 538 F. Supp. 3d 826, 831–33 (N.D. Ill. 2021), illustrates the approach in a case involving claims similar to those asserted here. That court held that the FDCA preempted the plaintiff's claims alleging that state law required additional disclosures that the infant version of the defendant's product was identical to the children's version. *Id.* at 833. Like Plaintiff here, the plaintiff in *Harris* argued that her claims were consistent with the FDCA because the Act prohibits "labeling [that] is false or misleading," and she alleged that the product's labeling was false or misleading. *Id.* at 831 (cleaned up). Observing that the plaintiff "misses the points of preemption," the court found that the product's labeling indicated that it was safe for infants in accordance with the monograph, and that the plaintiff was "asking [defendant] to state more than that; namely, that the Infants' Product is the same product as the Children's Product. Simply put, [the plaintiff] is asking more than what the [monograph] requires." *Id.* at 833.[1]

Under this approach, the FDCA would preempt Plaintiff's claims that children's VapoRub and VapoCream require a disclaimer that it is the same as the non-children's version. The monographs applicable to VapoRub, and the comprehensive regulations applicable to VapoCream, do not require product labels to disclose that the Children's

[1] The court in *Youngblood*, 2021 WL 3700256, at *3, relied on *Harris* and adopted similar reasoning where plaintiffs similarly argued that state law required additional disclosures that the infant version of the defendant's product was identical to the children's version. This Court distinguished *Youngblood* on the ground that the relevant monograph in that case required that acetaminophen products for children specifically denote that they are for children. *See* ECF No. 42 at 5 n.4. However, *Youngblood*'s reasoning did not hinge on that fact. Instead, *Youngblood* held that a state requirement is preempted where it deviates *at all* from an applicable monograph. *See Youngblood*, 2021 WL 3700256, at *3 (by requiring "clear disclosures that there is no pharmacological distinction" between the two products at issue, the plaintiffs pursue "additional, gratuitous representations [that] are not compatible with the FDCA and the FDA's false and misleading labeling provisions").

product has the same formulation as the product that does not specify an age group. In other words, preemption applies "[b]ecause the [relevant FDA regulation] does not require any specific disclaimers concerning . . . the interchangeability of the two products at issue." *Harris*, 538 F. Supp. 3d at 833.

Second, other courts have held that federal law preempts a plaintiff's claim that a product is false or misleading if the FDA has actually considered or regulated the subject matter of the labeling issue raised by the plaintiff in some way, even if the additional representation the plaintiff would require is not inconsistent with federal labeling requirements. *See, e.g.*, *Goldstein*, 637 F. Supp. 3d at 111 (finding false and misleading claim preempted because "the FDA need not have dealt with the specific representation at issue in order to have 'regulated' 'the subject matter,' of the alleged misrepresentation, or the 'substance of [the] representation'") (citations omitted); *Baker v. Nestle S.A.*, 2019 WL 960204, at *1–2 (C.D. Cal. Jan. 3, 2019) (finding claims preempted even though FDA did not address specific representation at issue because regulations allowed for representation that was similar to the representation); *Morgan v. Albertsons Cos., Inc.*, 2023 WL 3607275, at *6 (N.D. Cal. Mar. 13, 2023) (similar); *Sapienza v. Albertson's Cos., Inc.*, 2022 WL 17404919, at *3 (D. Mass. Dec. 2, 2022) (finding claims preempted because "FDA preemption regulates dissolution standards generally—the subject matter of [Plaintiff]'s state-law claims"); *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 320 (S.D.N.Y. 2017) ("Where federal law specifically regulates the subject matter of a plaintiff's state law claims, and those claims seek to impose requirements not identical to federal requirements, those state law claims are preempted."); *Bimont v. Unilever U.S., Inc.*, 2015 WL 5256988, at *2–3 (S.D.N.Y. Sept. 9, 2015) (recognizing that, if the FDA "regulates a given subject matter," all non-identical state laws applicable to drugs or cosmetics "within that subject matter" may be preempted).

Preemption would apply here under this approach as well. The FDA has regulated the relevant subject matter through the regulations governing cosmetics like VapoCream

and the monographs for antitussives and analgesics governing VapoRub. *See* 21 C.F.R. § 701 *et seq.*; *id.* §§ 341.74, 341.40. On this approach, the FDA's regulation of the subject matter is sufficient to trigger preemption. It does not matter that these regulations do not specifically say whether a disclaimer is needed that the children's and non-children's versions are the same, because "the FDA need not have dealt with the specific representation at issue in order to have 'regulated' 'the subject matter.'" *Goldstein*, 637 F. Supp. 3d at 111 (cleaned up). A court applying this approach might instead focus, for instance, on the fact that the applicable FDA monograph requires the same labeling and dosing instructions for children and adults for products like VapoRub, while for *other* products it prescribes distinct labeling requirements for children's products. In other words, the FDA considered the question of how children's and non-children's versions of these products should be labeled—the subject matter of Plaintiff's claims—and it opted not to require the specific disclaimer Plaintiff claims here is required by state law.

Third, some courts have declined to hold that a plaintiff's claim is preempted if an FDA monograph or regulation does not directly address the specific representation that the plaintiff's claims would require. *See, e.g.*, *Slaten*, 2023 WL 3437827, at *2 (holding that FDCA did not preempt claims because no FDA regulation addressed labeling representations for duration of effectiveness of product—"no FDCA requirement 'on point,' so no preemption"). On this view, absent a specific federal regulation on point, a court would view federal and state law as imposing an identical requirement, at a high level of abstraction, for the product to not be false or misleading. *See Jovel*, 2013 WL 5437065, at *6 ("a claim that [defendant's] representations are false or misleading does not impose a requirement other than those imposed by federal law").

This Court did not follow the first approach, on which preemption would apply because the governing federal regulations "do[] not require any specific disclaimers" of the kind that Plaintiff says state law requires here. *Harris*, 538 F. Supp. 3d at 833. This Court also did not follow the second approach, because it did not consider it relevant that the FDA

has regulated the "subject matter" of labeling children's versions of the products, despite not "deal[ing] with the specific representation" Plaintiff challenges in this case. *Goldstein*, 637 F. Supp. 3d at 111. The Court instead followed the approach taken by the *Slaten* and *Jovel* courts. In the main text of its opinion, the Court viewed Plaintiff's "state-law requirements [as] identical to those imposed by the FDCA" because the Act prohibits false or misleading representations, and Plaintiff alleges that P&G's Vapo Products are false or misleading for lack of a disclaimer that the children's and non-children's versions are the same. ECF No. 42 at 4. Additionally, in a footnote, the Court noted that "the FDA does not address whether antitussives and external analgesics for children must specifically denote that they are for children." *Id.* at 5 n.4. Thus, like in *Slaten* but unlike in many of the other cases cited above, the Court reasoned that preemption does not apply because the FDA regulations do not specifically "address" the disclaimer that Plaintiff contends should have been provided.

Since this Court's preemption ruling adopted one side of a legal debate on which courts are "heavily split," *id.* at 4, there are substantial grounds for a difference of opinion on the preemption question.

2. There Is Substantial Ground for Difference of Opinion on Whether Plaintiff Has Standing to Sue for False Advertising Injuries Stemming From a Product She Never Purchased.

Courts have found that there is substantial ground for difference of opinion on questions for which "[n]o binding authority resolved [the] dispute." *E.g.*, *FERC v. Vitol Inc.*, 2022 WL 583998, at *1, *4 (E.D. Cal. Feb. 25, 2022) (certifying order due to absence of binding authority); *see also In re Kenny G. Enterprises, LLC*, 2014 WL 908709, at *3 (C.D. Cal. Mar. 6, 2014) (finding substantial ground for difference of opinion "[g]iven the earnest split of authority and lack of guiding precedent"); *Waste Mgmt. of Louisiana, L.L.C. v. Parish*, 2014 WL 5393362, at *4 (E.D. La. Oct. 22, 2014) (same); *Associated Indus. Ins. Co. v. Brad Williams, LLC*, 2018 WL 2308767, at *8 (S.D. Miss. May 21, 2018) (same).

As this Court acknowledged, "[t]here is no clear binding authority on whether plaintiffs have standing to sue for products they did not purchase." ECF No. 42 at 10. Consequently, "[c]ourts in this circuit have diverged on the question of whether [such] a named plaintiff has standing." *Donohue v. Apple, Inc.*, 871 F. Supp. 2d 913, 921 (N.D. Cal. 2012).

Various courts have categorically denied standing as a matter of law for plaintiffs asserting claims for products they did not purchase. *See, e.g.*, *Dysthe*, 2011 WL 5868307, at *4 (holding that plaintiff could not "show[ ] any harm suffered as to this product" because she never purchased product); *Granfield v. NVIDIA Corp.*, 2012 WL 2847575, at *6 (N.D. Cal. July 11, 2012) ("when a plaintiff asserts claims based both on products that she purchased and products that she did not purchase, claims relating to products not purchased must be dismissed for lack of standing."); *Mlejnecky v. Olympus Imaging America Inc.*, 2011 WL 1497096, at *4 (E.D. Cal. Apr. 19, 2011) (same); *Carrea v. Dreyer's Grand Ice Cream, Inc.*, 2011 WL 159380, at *3 (N.D. Cal. Jan. 10, 2011) (same).

Other courts, including this one, have held that a plaintiff does have standing to sue over products they did not purchase if the product and allegations concerning it are substantially similar to the other products and their accompanying allegations in the case. *See, e.g.*, *Miller v. Ghirardelli Chocolate Co.*, 912 F. Supp. 2d 861, 869–70 (N.D. Cal. 2012) (describing division of authority, asking whether "the five products and the alleged misrepresentations about them are sufficiently similar so that [the plaintiff] has standing as to the four products he did not buy," and concluding that the products not purchased were not sufficiently similar); *Astiana v. Dreyer's Grand Ice Cream, Inc.*, 2012 WL 2990766, at *13 (N.D. Cal. July 20, 2012) (adopting the same standard and concluding that plaintiffs "alleged sufficient similarity between the products they did purchase and those that they did not" for standing); *Forcellati v. Hyland's, Inc.*, 876 F. Supp. 2d 1155, 1161 (C.D. Cal. June 1, 2012) (finding the "argument is better taken under the lens of typicality or adequacy of representation" at the class certification stage "rather than standing"); *Donohue*, 871 F.

Supp. 2d at 922 (finding that such "issues [] are better resolved at the class certification stage").

Given the divergent positions taken by courts on the standing question and the absence of binding precedent, a substantial ground for difference of opinion is evident here.

C. Interlocutory Review May Materially Advance the Ultimate Termination of the Litigation.

The last criterion under Section 1292(b) is also met here. Interlocutory review may "materially advance" the litigation because immediate resolution of either or both these issues "may appreciably shorten the time, effort, or expense of conducting the district court proceedings." *ICTSI Oregon, Inc. v. Int'l Longshore & Warehouse Union*, 22 F.4th 1125, 1130–31 (9th Cir. 2022) (cleaned up). Plaintiff's claims concerning VapoRub and VapoCream are at the heart of this case: together, they make up 92% of the sales alleged to be at issue. *See* Cullinane Decl. ¶ 4. If one or both aspects dropped out of the case, the result would be a substantially different and narrower case that would be much easier to resolve.

An interlocutory appeal need not dispose of the entire case; the question is only whether it may materially advance the ultimate termination of the litigation. *See, e.g.*, *Gillespie,* 2022 WL 18584762, at *3 (resolving some, but not all, claims would materially advance litigation); *Rollins v. Dignity Health*, 2014 WL 6693891, at *4 (N.D. Cal. Nov. 26, 2014) (noting that "the considerations of this factor overlap significantly with the first one" and that immediate appeal would materially advance the litigation because resolution of certified issue "will clearly impact the course of further motions and discovery"); *accord Reese*, 643 F.3d at 688 ("a final, dispositive effect on the litigation" is not required).

Immediate appellate review of the federal preemption and Article III standing questions would clarify the nature and scope of the remaining claims, making ultimate resolution easier and streamlining discovery to minimize the burden on the parties and the Court. Resolving the preemption issue in P&G's favor would remove from the case the two

products from which the bulk of the alleged damages arise. *See* Cullinane Decl. ¶ 4. And resolving the standing issue in P&G's favor would remove one of those products from the case.

Courts have agreed that an interlocutory appeal that significantly narrows the scope of the case materially advances the termination of this litigation. When an appeal could resolve issues affecting the bulk of the damages sought, resolution of those issues can incentivize the parties to consider settlement as an efficient means of resolving the remaining claims. *See Mercury Interactive*, 2011 WL 1335733, at *3 (finding that Section 1292(b) review would advance the termination of the litigation because resolution of an issue affecting "[t]he bulk of the damages sought" "would have a significant effect . . . upon the parties' efforts to reach settlement"). Additionally, the involvement of fewer products reduces the complexity and costs of discovery, as parties can focus their efforts specifically on the remaining product. *See Ritz Camera*, 2011 WL 3957257, at *3 (granting certification because Court agreed with Defendants that appeal could "avoid expensive and protracted discovery"); *Rollins*, 2014 WL 6693891, at *4 (similar). An immediate appeal on these issues could "'minimiz[e] the total burdens of litigation on [the] parties and the judicial system by accelerating or at least simplifying trial court proceedings.'" *Dukes v. Wal-Mart Stores, Inc.*, 2012 WL 6115536, at *5 (N.D. Cal. Dec. 10, 2012) (quoting 16 Wright & Miller, *Federal Practice & Procedure* § 3930 (2d ed.)).

A case reduced to only claims concerning VapoPatch—which comprises only 8.0% of the sales at issue, *see* Cullinane Decl. ¶ 4—would be a different case entirely, vastly reduced in scale and complexity and likely much easier to resolve. Accordingly, interlocutory review of the preemption and/or standing issues would materially advance the termination of the litigation.

IV. CONCLUSION

This Court should certify its Order of December 20, 2023 Granting in Part and Denying in Part Motion to Dismiss (Dkt. 42) for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) to address the following questions:

1. Whether the Federal Food, Drug, and Cosmetic Act expressly preempts state-law requirements to make additional disclosures on the label of an over-the-counter medicine or cosmetic, when the Food and Drug Administration has issued a monograph or other comprehensive regulations governing the product that do not impose the labeling requirement sought by the plaintiff.
2. Whether a plaintiff who has never purchased a particular product has Article III standing to sue for alleged false advertising concerning that product.

DATED: January 25, 2024

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CERTIFICATE OF COMPLIANCE

The undersigned, counsel of record for P&G, certifies that this brief is fewer than 25 pages, which complies with Judge Gee's Initial Standing Order. *See* ECF No. 11.

DATED: January 25, 2024

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